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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,991	03/28/2001	Maurice Zauderer	1821.0050004	9763

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EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,991	ZAUDERER ET AL.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,22-30,43-61,65-68,73-88 and 138* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 22-30, 43-61, 65-68, 73-88, 138* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/27/05, 4/27/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment and the response filed on 4/27/05 have been fully considered and entered into the application.

2. Claims 62, 64, 89-109 have been canceled by the amendment filed on 4/27/05. Claims 11-21, 31-42, 62-64, 440-137 have been canceled. Claims 1-10, 22-30, 43-61, 65-68, 73-88, 138 are currently pending in this application.

3. Claims 1-10, 22-30, 42-61, 64-88 and 138 are currently being examined in this application.

4. Applicant's response regarding the requirement of new oath and declaration has been considered and this requirement has been with drawn.

5. The written description rejection of record has been maintained for the reasons of record.

Response to Arguments

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Applicant's arguments filed on 4/27/05, regarding the written description rejection have been fully considered but they are not persuasive.

Claims 1-10, 22-30, 43-62, 64-68, 73-88, 138 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

The instant claim briefly recites a method of selecting a target polynucleotide comprising, a) introducing into a population of mammalian host cells a library of insert polynucleotides; the library is constructed in a poxvirus vector or a adenovirus vector or a herpesvirus vector; and the expression of target polynucleotide in the host cell promotes cell death; b) culturing the host cells and c) collecting the insert polynucleotides from host cells, and the cell death is not the result of a cytotoxic T lymphocyte induced lytic event.

The instant specification discloses the use of linear DNA virus vector such as vaccinia virus vector, and the cell death is the result of expression of a suicide gene product by the host cell. The specification discloses the 'tri-molecular recombination' method in the method of identifying the target polynucleotide. The specification discloses that the suicide gene product is diphtheria toxin A subunit.

The specification discloses 'tri-molecular recombination' using modified vaccinia virus vectors. The specification discloses that vaccinia virus vectors currently are not used for identifying genes of interest from cDNA or other library, because high efficiency, high titer producing cloning does not exist in vaccinia (i.e., see 0324). The specification further discloses 'tri-molecular recombination is novel, high efficiency, high titer producing method of cloning vaccinia virus (i.e., see 0325). he specification examples of non-catalytic CD4+ T lymphocytes are all drawn to use of vaccines virus vectors in trimolecular recombination method, and suicidal gene. The specification description is directed to the use of specific Vaccinia virus vectors (especially vaccinia WR vectors) in trimolecular –recombination method, which clearly do not provide an adequate representation regarding the open ended claimed method for selecting a target polynucleotide of the instant claims. The specification description is directed to hypothetical methods of selecting target polynucleotides using trimolecular recombination method in selecting polynucleotides. The specification has no working examples of the instantly claimed method using the library of either pox virus vectors, adenovirus vector or a herpes virus vector, which is inserted into mammalian cells and collecting inserted polynucleotides from the dead host cells, and the cell death is not the result of a cytotoxic T lymphocyte induced lytic event.

> With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that a Awritten description of an invention involving a chemical genus, like a description of a chemical species, >requires a precise definition, such as by structure, formula [or] chemical name,= of the claimed subject matter sufficient to distinguish it from other materials.≅ *University of California v. Eli Lilly and Co.,* 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel,* 25 USPQ2d 1601,

1606 (Fed. Cir. 1993) (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)].

Although directed to DNA compounds, this holding would be deemed to be applicable to the instant method of screening; which requires a representative sample of showing of sufficient identifying characteristics of the products used to demonstrate possession of the claimed generic(s) and to demonstrate possession of products identified using the claimed method.

In the present instance, the claimed invention contains no identifying characteristics regarding the identified polynucleotide or the library of insert polynucleotides used.

Additionally, the narrow scope of examples directed to the use of specific vaccinia virus vectors in tri-molecular-recombination method, which are clearly not representative of the scope of the presently claimed method.

Applicants traverse the rejection, however, amended claim 1 to recite "wherein said library is constructed in a poxvirus vector... '. Applicants further argue that the specification describes several numerous other poxviruses, which can be used in the claimed method.

Applicant's arguments have been fully considered and are not persuasive. The specification in page 46, in paragraph 0293 discloses 'poxvirus' in general, and further paragraph 0294 discloses the vaccinia virus vector and particularly the vaccinia virus vectors, which are developed to perform trimolecular recombination, are preferred. And the specification has not disclosed any working examples of all the different types of vectors used in the claimed method. Thus, the specification lacks written description of use of any type of pox virus vectors in the claimed method of selecting polynucleotides, from cells which undergo cell death and the cell death is not a result of a cytotoxic T lymphocyte induced lytic event.

A "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species) (See MPEP 2163).

Applicants further argue that the specification in page 52 discloses other methods of constructing libraries using vaccinia virus vectors; and further argue that the method may not be as efficient as tri-molecular recombination, there is not requirement in the claims for a particular titer or recombination efficiency. Applicants arguments have been fully considered and are not persuasive, because the instant specification has not disclosed any examples of different types of vectors in the claimed method of identifying polynucleotides whose expression causes host cell death and the cell death is not a result of cytotoxic T lymphocyte induced event. An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118.

"[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated.").

Thus, in view of the guidelines in the MPEP, the instant specification neither given working examples of the claimed method, nor disclosed the specific vectors, and specific method steps of the instant claimed method. The specification has not disclosed the use of different poxvirus vectors in the method of selecting polynucleotides, which cause cell death. And further the specification has not disclosed the polynucleotides identified using the claimed method, and the polynucleotides cause cell death.

Applicants further assert that it is not necessary to describe the identifying characterisitics of potential target nucleotides because the claims are not directed to these target polynucleotides

per se, but rather they are directed to a method of selecting them, without any foreknowledge of what their identifying characteristics may be. Applicant's assertions have been fully considered and are not persuasive. Since the polynucleotides identified by the claimed method have to have apoptotic property, and the specification discloses that the functionally and/or structurally known genes or gene products are cloned into the vaccines virus vectors.

The specification specifically discloses that 'the vaccinia virus vectors are not used to identify previously unknown genes from a complex population of clones, such as cDNA or other library... '; and the use of vaccinia virus vector has been limited to the cloning of previously isolated DNA for the purpose of protein expression and vaccine development' (see page 52, 0310 of the specification). Thus, from the specification disclosure it is clear that the vectors are used to clone genes whose structure and function are known.

Further the disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406 (written description requirement not satisfied by merely providing "a result that one might achieve if one made that invention"); in re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming a rejection for lack of written description because the specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate").

Applicants refer to a list of suicide genes and toxic gene products that can be used to identify target polynucleotides (see page 17 of the response filed on 4/27/05). Applicant's arguments have been considered and are not persuasive, since the instant claimed method does not use

different target/analyte to identify the target polynucleotides (apoptotic genes). It is not clear whether applicants mean the suicide genes (listed in the response page 17) is required to identify the apoptotic polynucleotides or target polynucleotides of the instant claimed method. Applicants further argue that the 'requirement of 'working examples is an in correct application of the law with respect to written description requirement.

*Applicant's arguments regarding the working examples have been considered and are not persuasive. Examiner agrees that 'working examples is not a requirement for written description requirement', however in the unpredictable arts such as in the recombinant technology adequate written description may be met by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. Cooper v. Goldfarb, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). See also UMC Elecs. Co. v. United States, 816 F.2d 647, 652, 2 USPQ2d 1465, 1468 (Fed. Cir. 1987) ("[T]here cannot be a reduction to practice of the invention * * * without a physical embodiment which includes all limitations of the claim."); Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997) ("[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose."); Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996). The instant specification has not disclosed that the polynucleotides identified using the claimed method or the working examples in which the claimed method is used to identify the polynucleotides. Thus, the written description rejection has been maintained for the reasons of record.*

Conclusion

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

11 July 2005

PADMASHRI PONNALURI
PRIMARY EXAMINER